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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/059,390	01/31/2002	Burton H. Sage JR.		2538

7590 09/09/2004

BURTON H. SAGE, Jr.  
3430 BERNARDINO LANE  
VISTA, CA 92084

EXAMINER

NASSER, ROBERT L

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 09/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	10/059,390	SAGE, BURTON H. <span style="float: right;">ON</span>	
	Examiner	Art Unit	
	Robert L. Nasser	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 27 May 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-40 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 37 and 39-40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant has referred to the dwell time in the needle in these claims. The examiner can only find reference to the dwell time in the mixing chamber 6 in the disclosure. Hence, there is no adequate support for the claimed subject matter and the amendment constitutes new matter.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 7, 11, 16-19, 23, 27, 30-34, 36, and 38 are rejected under 35 U.S.C. 102(b) as being anticipated by Albery et al 5462645. Albery et al has a device including a dialysis needle 1, having sidewalls that are semi permeable, an analysis chamber 6, and a inlet channel 10. A micro pump moves a perfusate (electrolytic solution) from a reservoir into the needle, where it is periodically mixed with a reagent solution (see column 5, lines 37-54). The examiner notes that the portion of the device

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on the interior of the needle lumen is a mixing chamber. Hence, the mixture is mixed before being provided to the analysis chamber 6. In addition, the device is calibrated by supplying calibration fluid and mixing it with an enzyme (see column 6, lines 26-37 and column 7, lines 7-14). The examiner notes that the calibration is performed first and then the first measurement. Hence, at least for the first measurement, the calibration and measurement are alternately performed.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4, 8, 20, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Albery et al in view of the Zahn et al article entitled "An integrated Microfluidic Device for the Continuous . . ." Zahn shows a microdialysis needle having a polysilicon membrane and having a silicon needle made from an etch process in part. From this teaching, it would have been obvious to modify the Albery to use the needle of Zahn, as it is merely the substitution of one known equivalent needle for another.

Claims 5, 6, 21, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over in view of Korf et al. Korf et al shows a similar analyte measuring device that has a strap to allow it to be worn, so as to allow the user to remain mobile while using. From this teaching, it would have been obvious to modify the Albery to use such a strap, to allow the user to be ambulatory and function normally while using.

Claims 9, 10, 25, 26, 37 and 39-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Albery et al.

Claims 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Albery in view of Roeper et al. Roeper et al teaches the equivalence of optical sensor and electrochemical sensors in devices like that of Albery. Hence, it would have been obvious to substitute an optical sensor (column 4, lines 1-7), as it is merely the substitution of one known equivalent sensor for another.

Claims 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Albery in view of Roeper et al and Ehwald et al. Roeper et al teaches in column 4, lines 1-7 that known sensors may be substituted for the electrochemical sensor in a device like that of Albery. Ehwald teaches that viscometer is a known device to measure glucose. Hence, it would have been obvious to modify the above combination to use a viscometer, as it is merely the substitution of one known equivalent sensor for another.

Claims 12-13 and 28-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Albery et al in view of Skrabal. Skrabal teaches a device like that of Albery that measures glucose and has an insulin pump 12 that pumps insulin into the patient in response to glucose measurements. Hence, it would have been obvious to modify Albery to use such an automated infusion method and device, to improve the treatment of diabetes.

Claims 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over Albery et al in view of Effenhauser et al. Effenhauser et al teaches in vivo calibration, which eliminates the need to remove the device for recalibration. Hence, it would have been

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obvious to modify Albery to use in vivo calibration, to extend the useable life of the device. The frequency of measurement versus calibration would have been obvious to one skilled in the art.

Applicant's arguments filed 5/27/2004 have been fully considered but they are deemed moot in view of the new grounds of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert L. Nasser whose telephone number is (703) 308-3251. The examiner can normally be reached on Mon-Fri, variable hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (703) 308-3130. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert L. Nasser  
Primary Examiner  
Art Unit 3736



ROBERT L. NASSER  
PRIMARY EXAMINER

RLN  
March 5, 2004